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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,990	08/27/2003	Murty Mangena		6744

7590
Dr. Murty Mangena
518 Codell Drive
Lexington, KY 40509

04/02/2008

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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04/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/649,990	Applicant(s) MANGENA ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 March 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 03 March 2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1,4-8,10-18 and 20.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☒ Note the attached Information *Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). 03/03/08
13. ☐ Other: _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: applicant's arguments are not persuasive. Applicant argues that only the selection of the conditions recited in amended claims 1 and 17 would lead one to arrive at the product, but it is noted that the pH recited is a range and falls within physiological pH and it is further noted that Later teaches two different viscosities of PLGA. Regarding applicant's argument that there is no motivation to pick buprenorphine free base from the long list of possible actives, it is noted that any of the drugs can be formulated according to the process of Lawter with buprenorphine specifically named and the list is finite such that the use of buprenorphine in the contemplated compositions has reasonable expectation of success using PLGA's having the viscosities taught in the examples. While Lawter did not teach the mixture of PLGA having the different viscosities, Lawter teaches the use of PLGA's with different viscosities so that a combination of PLGA's with the active agent would have reasonable expectation of success. Regarding applicant's argument that Oshlack does not overcome the deficiency of Lawter, it is noted that Oshlack is relied upon for formulating buprenorphine with polyvinyl alcohol and not for teaching the use of PLGA with the buprenorphine. Applicant appears to have different reasons why Oshlack is combinable with Lawter while the office action combines the specific teachings of Oshlack, that is, PVA with buprenorphine with buprenorphine and PLGA. Similarly the Hill reference is relied upon for teaching buprenorphine formulation that contains PVA and that is the reason for combining Lawter with Hille to arrive at a composition that contains buprenorphine, PLGA's having the different viscosities and PVA. Furthermore, regarding the pH, it is noted that Lawter's release medium is at 7.4 (column 6, lines 62 and 63) and pH of between about 6.8 to about 8 and spans the pH of physiological milieu and is within the technical skill of the artisan to formulate buprenorphine at a pH within acceptable pH for buprenorphine.

The examiner acknowledges receipt of IDS filed 03/03/08. Applicant's statement of the substance of the interview is substantially correct.

/BF/